DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 23, 2014

Topcon Corp.
% Ms. Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K141325
Trade/Device Name: Trc-nw8f Plus Non-mydriatic Retinal Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: September 11, 2014
Received: September 12, 2014

Dear Ms. O'Connell,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141325

Device Name
NON-MYDRIATIC RETINAL CAMERA TRC-NW8F plus

Indications for Use *(Describe)*
The Non-Mydriatic Retinal Camera TRC-NW8F plus is intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eye care professional, with the use of a mydriatic or without the use of a mydriatic.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Non-Mydriatic Retinal Camera TRC-NW8F plus

510(k) Owner
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Date Prepared: September 11, 2014

Name of Device
Non-Mydriatic Retinal Camera TRC-NW8F plus

Common or Usual Name
Retinal Camera

Classification Name
Camera, Ophthalmic, AC-Powered
21 C.F.R. 886.1120
Product Code: HKI

Predicate Devices
Non-Mydriatic Retinal Camera TRC-NW8F (K100207)
Retinal Camera TRC-50DX (K123101)

Indcations for Use
The NON-MYDRIATIC RETINAL CAMERA TRC-NW8F plus is intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eye care professional, with the use of a mydriatic or without use of a mydriatic.

Technological Characteristics
The Topcon TRC-NW8F plus is a fundus camera designed to observe, photograph and record the fundus oculi of a patient's eye with or without the use of a mydriatic. The TRC-NW8F plus does not come into contact with the patient's eye and provides the fundus oculi

image information as an electronic image for later analysis. The TRC-NW8F plus performs color photography, fluorescein fundus angiography and Autofluorescence (FAF) photography. This product is equipped with an observation monitor used for observation purposes and display of a photographed images. The TRC-NW8F plus uses an attached commercial digital single-lens reflex camera to photograph or record the fundus oculi of a patient. A built in digital camera is used for taking autofluorescence images. The TRC-NW8F plus is only to be used with the Nikon D7000 digital camera.

A photographed image may be recorded on a commercial memory card built into a commercial digital single-lens reflex camera, a personal computer or commercial memory device (flash memories, hard disc, etc.). A commercial digital printer is connected and can print the observed images and the photographed images of the fundus.

Performance Data

The TRC-NW8F plus has been tested and found in compliance with the following recognized consensus standards:

AAMI ANSI ES 60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance;

IEC 60601-1-2: 2007 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance: Collateral Standard: Electromagnetic Capability – Requirements and Tests;

ISO 15004-1:2006 Ophthalmic instruments – Fundamental requirements and test methods – Part 1: General requirements applicable to all ophthalmic instruments;

ISO 15004-2:2007 Ophthalmic Instruments – Fundamental requirements and test methods – Part 2: Light hazard protection;

ISO 10940: 2009 Ophthalmic instruments - Fundus cameras

An analysis was performed of images captured with the TRC-NW8F plus and the predicate device which were formally evaluated and it was found that model eye images from the TRC-NW8F plus and from the predicate device were either equivalent or similar in terms of sharpness, image focus and chart readings. The results from the grading of clinical images from the TRC-NW8F plus were either equivalent or were similar for the predicate devices. This study demonstrated that the TRC-NW8F plus with a digital cameras and imaging mode is substantially equivalent to the predicate devices.

Substantial Equivalence

The TRC-NW8F plus has the same intended use and indications for use, and similar technological characteristics and principles of operation as the TRC-NW8F and the TRC-50DX. Although there are minor differences between the TRC-NW8F plus and the predicate devices, those differences do not raise new questions of safety or efficacy. Thus,

the TRC-NW8F plus is substantially equivalent. Performance data demonstrates that the TRC-NW8F plus is as safe and effective as the TRC-NW8F. The image grading results of autofluorescence images show that the TRC-NW8F plus is equivalent to the TRC-50DX for autofluorescence imaging. Thus, the TRC-NW8F plus is substantially equivalent to its predicate devices.